

**REMARKS**

The pending Office Action addresses claims 1-40, rejecting claims 1, 3, 7, 8, 10, 11, 14-20, 22, 25, and 28-40. Claims 2, 4-6, 9, 12, 13, 18, 23, 24, and 27 are withdrawn from consideration for being directed to a non-elected species of the invention. By this amendment, claims 1, 7, 8, 29, 32, and 34 are amended to replace the term “fluid delivery pathway” with “fluid delivery *line*.” Support for these substitutions can be found on page 13, lines 1-3. Accordingly, no new matter is added by these amendments.

For all the following reasons, Applicants respectfully request reconsideration of the present application in view of the current amendments.

***Election/Restrictions***

Applicants note with appreciation the Examiner’s indication that claim 1 is now deemed to be generic to all species of the present invention.

***Rejections under 35 U.S.C. §102***

The Examiner rejects claims 1, 3, 7, 8, 10, 11, 14-20, 22, 25, and 28-40 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,491,666 to Santini, Jr. et al. (hereinafter the “Santini” reference). For the following reasons, Applicants respectfully request reconsideration and withdrawal of the pending rejection under Santini.

By way of introduction, Applicants’ invention is directed to an implantable drug delivery system that enables an effective amount of a desired drug to be delivered to the target treatment site, without substantially diminishing the concentration of the drug during the delivery process. To accomplish this goal, the delivery system includes a fluid delivery pathway or line that extends from the drug reservoir to the immediate vicinity of the target site. When a drug is released from the reservoir, it travels to the target site via the delivery line without substantial dilution (i.e., since the drug does not travel to the target tissue region by diffusion, the treatment concentration of the drug can be maintained). As described in Applicants’ specification, this delivery pathway or line can take the form of, for example, an implantable conduit, catheter, or tube. (*See*, page 4, lines 28-32; page 5, lines 19-22; page 8, lines 4-8). This key concept is

reflected in each of the independent claims (claims 1, 29 and 40), and is discussed in greater detail below.

Independent claims 1 and 29 originally required a “fluid delivery pathway” extending from an infusion pump to the target tissue site, the pathway being configured such that the drug material is released into the pathway and discharged from the pathway to the target tissue site. Independent claim 40 requires a “delivery line” that connects to an infusion pump and is implantable at a target tissue site, the delivery line being in communication with the drug release device such that the drug is delivered to the target site by way of the delivery line.

Despite these specific limitations in the claims, the Examiner fails to give proper weight and consideration to the limitations “fluid delivery pathway” and “delivery line,” and rejects them as being anticipated by Santini. Applicants respectfully disagree because Santini does not disclose any kind of *implantable* drug delivery system having a *fluid delivery pathway* or *delivery line* whatsoever. However, in order to expedite prosecution and to even better define the present invention, Applicants have amended independent claims 1 and 29, as well as dependent claims 7, 8, 32, and 34, to require a “fluid delivery *line*” with the implantable drug delivery system of the present invention.

Santini fails to disclose an implantable drug delivery system having this required element. In particular, Santini fails to describe or suggest an *implantable* drug delivery system that includes a *fluid delivery line* that extends into the target tissue site for carrying the drug from the drug reservoir to the tissue site to be treated. Rather, Santini discloses several embodiments of drug delivery systems having a microchip as a drug reservoir. Where Santini’s drug delivery system (100) includes a fluid delivery catheter (116) for carrying a drug to the target site, such as in FIGS. 8A and 8B, the system (100) is not described as an *implantable* system, as is required of the claimed invention. And where Santini discloses an implantable drug delivery system, such as in FIG. 9A in which the microchip containing the drugs is attached to an implantable stent, Santini further fails to describe a fluid delivery line that carries the drug from the microchip to the target tissue site. Thus, Santini fails to describe or suggest a drug delivery system that is both *implantable*, and which includes a *fluid delivery line* that extends into the target tissue site, as are required of all the independent claims of the present invention.

Accordingly, Santini does not anticipate the claimed invention, because the Santini drug delivery system fails to meet all of the limitations of the claimed invention. The Examiner is respectfully requested to withdraw the rejections under Santini.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

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